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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,036	HAPP, DORRIE M.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *15-17,19,21,23,27-29,32,37 and 42-47* is/are allowed.

6)☒ Claim(s) *3,5,8,9,25,26,33,49 and 51* is/are rejected.

7)☒ Claim(s) *2,4,7,10,14,34,39-41,44,50 and 52* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 2-5, 7-10, 14-17, 19, 21, 23, 25-29, 32-34, 37, 39-47 and new claims 49-52 .

DETAILED ACTION

Examiner acknowledges receipt claim amendments and remarks filed 9/11/06. Claims 11, 24, 30, 31, 35, 36, 38 and 48 are canceled. Claims 5, 8, 9, 15, 19, 26, 27 and 33 are amended. New claims 49-52 are added. Claims 2-5, 7-10, 14-17, 19, 21, 23, 25-29, 32-34, 37, 39-47 and new claims 49-52 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3, 5, 8, 9, 25, 26, 33, 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanikanti et al. (US 5,900,425) in view of Sinclair et al. (US 5,760,118).

Claim 5 reads on a composition comprising a core and a coating layer. The first layer as recited in the claims read of a core containing an active agent and a polymer. The second layer of the claims read on a coating layer comprising a polymer. The recitation of "coating for medical device" is in the preamble and directed to the intended use of the composition and future intended use of the composition does not distinguish the instant composition from the composition of the prior art. The preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product/composition defined by the

remainder of the claim); STX LLC. v. Brine, 211 F.3d 588, 591, 54 USPQ2d 1347, 1350 (Fed. Cir. 2000).

Kanikanti teaches solid dosage composition comprising light sensitive active agents and a light protective coating (column 4, lines 7-14). The light sensitive active agent or drug is prepared with a polymer to obtain controlled release of the active agent or drug (column 2, lines 23-35, 52-67; column 3, lines 26-46), and this meets the limitation of the first layer in the generic claims. Kanikanti states that for "light sensitive active compounds, such as nifedipine and nimodipine, the controlled release tablets must then be provided with light protective coating in order that the active compound is not degraded by light." In Kanikanti, the coating is done with HPMC film forming polymer, PEG plasticizer and titanium oxide and iron oxide light scattering and absorbing pigments (column 4, lines 6-14). The disclosure of the protective coating meets the limitation of the second layer containing protective compounds in the generic claims.

The light sensitive drug as recited in claim 3 reads on the light sensitive drug, nifedipine and nimodipine disclosed by Kanikanti. "Having increased resistance to light and/or UV-radiation as recited in claims 8 and 9 is in the preamble and is a property of the composition, which the disclosed composition of the prior art would inherently possess. The protective coating layer of Kanikanti does not have a drug or active agent and Kanikanti thus meets the limitation of claim 25. In the absence of factual evidence, the ratio between the drug, the compound, and the drug recited in claims 26 and 33 is not inventive over the prior art composition.

While Kanikanti discloses using titanium dioxide and iron oxide as protective compounds, Kanikanti does not disclose the use of carbon black or titanium-nitride-oxide. However, Sinclair teaches that carbon black, zinc oxide and substituted benzophenones are UV-light absorbers which when added to a composition make the composition more resistant to degradation by ultraviolet radiation (column 31, line 67 to column 32 line 4).

Regarding the ratio of the light or UV protecting compound, it is noted that there is no demonstration in applicant's specification showing that certain amount of the light or UV-protective compound relative to certain amount of the polymer in the top-coating composition (recited ratios) provides unusual results to the coated medical device. For example, the specification at paragraph [0053] of the published application, states "the ratio, by mass, of the light- and/or UV-radiation protective compound to the polymer is between about 3 to 1 (at the lower range of concentrations of the solution to be sprayed) and about 1 to 3 (at the higher range)" without further description of what if any unexpected/unusual results the cited ration provides to the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the light protective compound of Kanikanti or that of Sinclair in the composition of Kanikanti since Sinclair with the expectation that in either case, the light protective coating would protect the light sensitive drugs/active agents of Kanikanti from being degraded by that UV-light.

2. Claims 2, 4, 7, 10, 14, 34, 39-41, 44, 50 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not disclose a stent.

3. Claims 15-17, 19, 21, 23, 27-29, 32, 37 and 42, 43, 45-47 are allowable because the prior art does not disclose the methods of claims 15, 19 and 28.

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER